Digital Data Flow (DDF) Initiative

Clinical Data Manager

Persona Toolkit

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Digital Data Flow (DDF) Initiative Overview

The Digital Data Flow (DDF) Initiative aims to catalyze digital transformation; breaking the protocol document paradigm to enable seamless data flow

Digitized Protocols

Enabling the use of technologies that identify and assemble study elements using a common, industry-standard digital language allows industry to move to digital protocols

Advanced Analytics

Better enabling the use of advanced analytics such as Artificial Intelligence and Machine Learning to improve study designs

Connectivity of Data and Processes

Enabling traceability, automated flow of content to key clinical documents, and automation to clinical & operational systems (e.g.. EDC, CTMS)

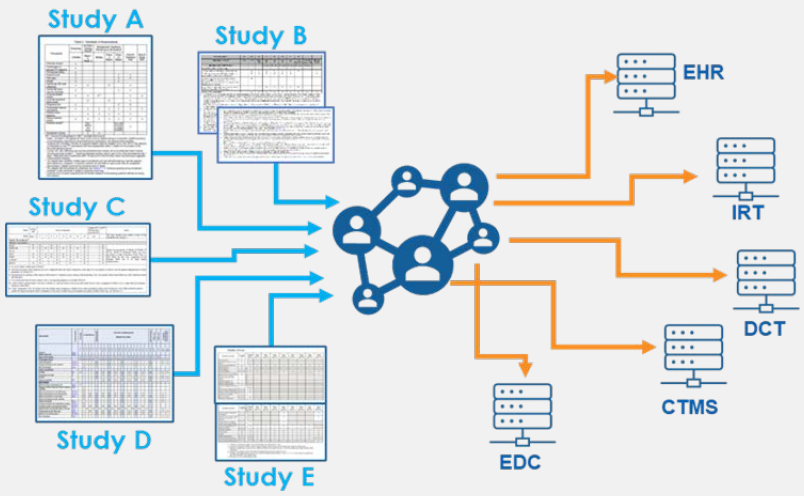
Open & Flexible Solution

A functioning, example solution to enable exchange of protocol info between systems that is vendor agnostic, flexible, and provided in open source

VISION: From Documents to Data: Write Once, Read Many Times

TODAY

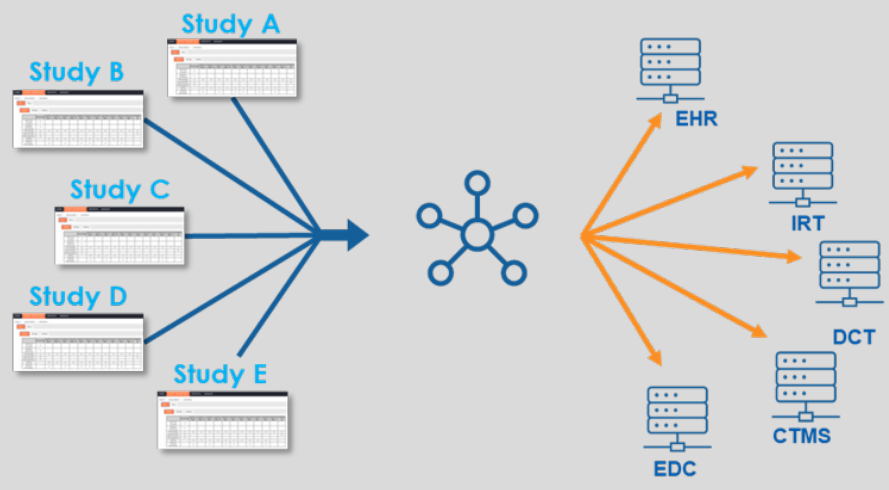
Many-to-many manual process; Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems



- *Schedule of Activities (SoA) specified **inconsistently** in study protocols (e.g., sections, rows, columns, footnotes)*
- ***Manual** process to configure systems/tools*
- ***No reliable method** to synchronize updates from a single source of truth*

TOMORROW

Digitalized one-to-many process; Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems



- ✓ ***Digitized design** specification per study*
- ✓ ***Consistent** method of study spec exchange*
- ✓ *Streamlined, **automated** start-up (reduce effort, cycle time, and complexity)*
- ✓ ***Improve** quality and compliance. Minimize protocol violations*

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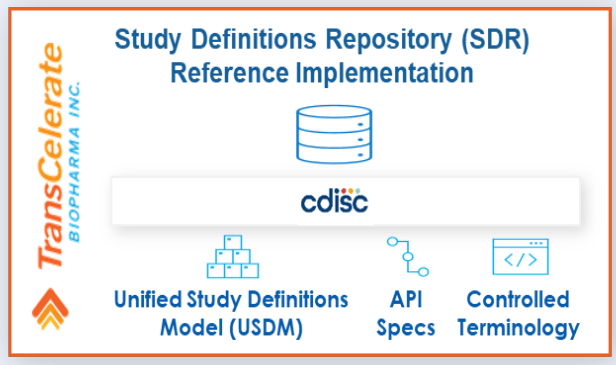
Digital Data Flow (DDF) Initiative Overview

Understanding Key Concepts

The Digital Data Flow Initiative offers a **mechanism to digitize clinical study components** to enable interoperability and reuse, starting with study design.

In collaboration with Clinical Data Interchange Standards Consortium (CDISC) and other stakeholders, TransCelerate has developed a standard data model that creates **a new digital language for specifying protocol information**, as well as a **demonstrated way to connect systems** that produce, exchange or consume this information.



Unified Study Definitions Model (USDM)

An industry standard for study definitions (protocol information) promulgated and maintained by CDISC

Study Definitions Repository Reference Implementation (SDR RI)

A functioning, example approach that utilizes USDM to manage the information flow of protocol data between upstream and downstream systems

Study Builder/ Digitized Study Design Solution

An application or piece of software utilized by a study team to design a study and/or author a study protocol

Controlled Terminology

CDISC developed set of codelists and valid values for terms used in a study

Application Programming Interface (API) Specifications

CDISC developed coding language to connect and exchange data between systems

Biomedical Concepts

CDISC and other organizations developed definitions of discrete units of biomedical information that would need to be measured for a study participant

Key Focus Areas on the DDF Roadmap

Digitization of Study Elements and Downstream EDC Automation (Current/Completed)

- ✓ Support electronically populating and configuring EDC/CRFs based on the digital protocol specification
- ✓ Use digital protocol specification to demonstrate (as a proof of concept) the population of elements in a human readable protocol document

Complete Protocol Digitization & Regulatory Alignment (In Progress)

Includes collaboration through HL7 Vulcan Working Group between ICH M11 & CDISC

- ➢ Complete (100%) digitization of all protocol elements in alignment with M11 and relevant CDISC SDTM domains
- ➢ Begins with gap analysis between USDM and ICH M11 content model, CDISC SDTM, and Global Trial Registry Reporting
- ➢ Goal to capture "breadth" of ICH M11 completely within USDM, followed by greater "depth" of structured content within model (e.g. structured I/E criteria)

Expand Downstream Connectivity (In Progress)

Includes collaboration with expanding community of tech solution providers across range of clinical solutions

- ➢ Further develop USDM to enable downstream connectivity with priority systems, enabling a future state of "write once, read many times"
- ➢ Work collaboratively with vendor ecosystem to better understand existing gaps & development requirements for the USDM

Alignment with Point of Care (In Progress)

Includes collaboration with Vulcan FHIR Accelerator

- ➢ Comparative assessment of USDM and FHIR
- ➢ Alignment of DDF and FHIR resources for end-to-end enablement of EHR workflow set-up and eSource

Digital Data Flow (DDF) Initiative
Persona Toolkit Overview for Clinical Data Manager

*Clinical Data Manager**

Typically responsible for study set up in an EDC system to collect, organize, manage, and validate incoming clinical data, as per the protocol content, and for overseeing and coordinating the associated clinical data capture processes.

PURPOSE

The objective is to help inform clinical data managers so they are better prepared & **can more fully realize the anticipated benefits** of the DDF initiative.

An understanding of automation and digitalization of the end-to-end study design process will help data managers understand the impact of DDF and help them **adapt their role and responsibilities to new ways of working** within an automated and digitalized study lifecycle.

TOOLKIT OBJECTIVE

Job titles, roles, & responsibilities can and will vary, often significantly, across companies. This document seeks to outline some discrete tasks commonly performed by the roles addressed in this document – Clinical Data Manager – and explain how the DDF initiative will likely impact these tasks.

This document does not seek to address all tasks performed by personas, nor does it seek to dictate or suggest to the persona how relevant tasks must or should be performed, as this will vary greatly across companies.

HOW TO USE THIS TOOLKIT

1. **Review each component** of the persona toolkit for a Clinical Data Manager.

2. **Understand the purpose and use of each toolkit component.** Sponsor companies can consider this a deep dive to understand how the DDF initiative will impact roles & mitigation factors to enable an adoption pathway for specific roles & personas.

3. **Use the persona toolkit as a guide.** The persona toolkit is illustrative and intended to serve only as a guide for sponsor companies. The application of this toolkit needs to be customized to fit your company's context, objective and organizational set-up.

TOOLKIT COMPONENTS

Persona Profile Card

Outlines the profile for a typical Clinical Data Manager's role and can be leveraged to understand how the role of a Data Manager may change within the anticipated context of the DDF initiative, including the benefits and value of DDF to the Data Manager role.

DDF Change Impacts

Identifies potential impacts of DDF to a Clinical Data Manager's role from current state (As-Is) to a future state (To-Be) which DDF will help make possible.

"Day in the Life" with DDF

What could a work-day look like with the application of DDF?

"Day in the Life" maps out an illustrative high-level flow of work across an average day for a Clinical Data Manager with the application of the DDF initiative.

** The Clinical Data Manager toolkit focuses on the responsibilities generally performed by the clinical data manager within the context of the study protocol and does not cover the broad swath of responsibilities of a clinical data manager in a pharma company*

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ASSUMPTIONS FOR USE OF CLINICAL DATA MANAGERS: PERSONA BUILD

Business Role

The persona covers a typical clinical data manager's role.

For the purpose of this toolkit, the responsibilities and activities of the clinical data manager role are focused primarily on EDC set-up, as an example, the full or partial automation of EDC study database set up and downstream migrations.

Clinical Standards Data Managers responsible for oversight of internal standards libraries and sub-specialties are not covered in detail within the scope of this asset.

Technical Role

This persona document assumes that EDC database systems are established within a company.

A solution/approach to digitize study design/protocol in a USDM** compliant format exists in the company's IT landscape.

An EDC software system exists that is capable of ingestion of digital protocol content flow in a USDM compliant format and automatically selecting an appropriate eCRF from an eCRF library.

Protocol Process

Data Managers are typically responsible for setting up a study in an EDC system and providing oversight of data collection and data quality.

Data managers are involved in understanding and reviewing the protocol and SOA during development stage.

Data managers have an awareness of their company's integrated system landscape, from protocol content creation to data flow into EDC systems, including any intermediary tools/data capture hubs.

Footnote: *This document refers to both the concepts of digitization and digitalization. Digitization refers to "digital-first documents and content", i.e., the transformation of non-digital content into a form computers can process. Digitalization refers to "digital-first processes and systems", i.e., the transformation of human-based and document-based processes into systems that can be computer-operated.*

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Assumptions about Clinical Data Manager Responsibilities

Pre-study activities: Contributes to Study Design, protocol review

Study start up programming: Sets-up SoA using selected standards, contributes to programming in EDC for eCRF design and data capture, edit checks, eCRF completion guidelines, DM reports

Study Conduct Management: Conducts amendment and migration management, data entry review, query management, data review of pivotal data (e.g., data delivery for primary and interim analysis, data monitoring committee), and narratives generation (depends on company ecosystem)

Data standards: Manages adherence to data standards

The Challenges Today

Process of taking study content information from protocol to set up of a study in EDC system is a **manual, tedious** end-to-end process that requires additional workflows.

It is costly, time consuming, prone to errors, and can lead to data inconsistencies, poor data quality stemming from low value data, and inadequate data-driven decisions.

How Can The DDF Initiative Help?

USDM** based automation could allow data managers to focus on higher value outcomes, **opening up opportunity for innovation** in data collection & quality strategy to potentially deliver optimal critical data at added cost & time efficiencies.

Digitization of protocols leads to an integrated and shorter study cycle workflow.

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CURRENT TO FUTURE STATE

CURRENT STATE

Today, manual efforts & interventions across the end-to-end process from protocol/study design to EDC and eCRF setup have resulted in **additional, redundant workflows and unstructured datasets** increasing chances of "dirty data" (inaccurate, inconsistent, duplicates, low value data).

FUTURE STATE

In the future, digitized protocols and SoAs will lead to automation of partial/full eCRF build in EDC systems. Automation and digitalization could **reduce overall cycle time** from final protocol to EDC database go-live.

BENEFITS & VALUE

Increased automation, digitalization, standardization, & enhanced collaboration could **reduce time-consuming, error-prone manual efforts & sync related efforts** (processes across upstream to downstream systems) to create an integrated clinical study cycle workflow with shorter cycle times.

With the DDF initiative, Clinical Data Manager roles have the **potential to move from tactical to strategic & value creating roles,** providing opportunities for innovation & improved productivity such as:

- ✓ Potential for continuous improvements in eCRF build, internal data standards and data analytics
- ✓ Possible optimization of protocol design, via USDM's digitization of biomedical concepts, could lead to fewer data entry queries & minimal data entry errors on low value data collected; potentially improving working relationships between site staff, trial monitors & data managers
- ✓ Possibility of reduced UAT & QC steps due to fewer manual updates could result in cost and time efficiencies
- ✓ Potential optimization of data quality with more focus on critical data such as study end points, potential for reduced data entry of non-critical fields and data cleaning via edit checks
- ✓ Greater opportunity for agile implementation of EDC updates with greater efficiencies, e.g., implementation of eCRF updates during COVID 19)
- ✓ Possible reduction or complete elimination of discrepancies between protocol data collection requirements and EDC/Clinical database setup
- ✓ Expedition and simplification of the end-to-end study design process from protocol to EDC with the use of USDM**, automation of study data flows
- ✓ Potential acceleration of ability to initiate data analyses due to faster availability to source data
- ✓ Possible improvements in EDC migrations with EDC automation replacing manual entry

POTENTIAL CHALLENGES

- ? Clinical data managers may be expected to align with information found in study builder tool upstream earlier in the process.
- ? Upfront initial training for USDM** could be required to upskill Data Managers on the common digital language for protocol information.
- ? Additional work could be required to curate historical protocol data from pre-USDM** clinical trials to make it available in a format that can be merged with USDM aligned data from more recent trials.

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Digital Data Flow (DDF) Initiative Change Impact

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PRE-STUDY ACTIVITIES

CURRENT STATE		FUTURE STATE***
Pre-study activities take place in a non-digital setup mostly reliant on manual protocol document		**Pre-study activities take place in a digitized protocol SoA needed to automate EDC build**
Protocol document is generally non-digital; protocol review, updates take place manually within a document.	PROCESS	Expect to shift to an automated EDC build using a digitized protocol SoA generated by upstream solutions. Process is automated by the USDM compliant SoA meta-data being automatically pushed into the EDC and matched to relevant eCRFs.
Non-digital document creation and management tools are typically used for pre-study activities.	TECHNOLOGY	The digitized protocol needed to automate EDC setup would be supported by Study Builder or a similar digitized study design solution.
Most common way of working continues to be in a manual protocol document creation, with input from multiple expert functions such as Stats. Relevant data from protocol document is manually extracted to complete EDC setup.	WAYS OF WORKING	Work would take place in an end-to-end digitized data structured protocol environment.

BIGGEST AREA FOR IMPACT

- Review of protocol **moves from a non-digital to a digital format**, including a digitized SoA.

RECOMMENDED ACTION FOR IMPACT

- **Communicate the value and benefits** of digitalization (successful use cases of using a digital protocol, highlighting cost, time, and data quality efficiencies) to create understanding of the DDF initiative and the USDM**.
- **Provide training and user guides** for process redesign, systems, and new skillsets that will be required for this change.

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STUDY START-UP PROGRAMMING

CURRENT STATE	FUTURE STATE***
Study startup programming takes place in a manual setup	**Study startup programming takes place in an accelerated digitized and automated environment**
SoA is set up by internal company standards selected, programming takes place in EDC for eCRF development and edit checks, eCRF completion guidelines, and DM reports. Manual documents are created.	**PROCESS** — EDC build is automated by enabling a digitized protocol SoA and automating eCRF generation. Reduction in the creation of manual documentation.
EDC system integrates with other systems, e.g., coding, CTMS.	**TECHNOLOGY** — Study definitions repository based on USDM exists as a stand-alone solution or integrated into an existing platform. Interoperability between study builder or similar alternate tool, EDC system, other systems, is made possible through the use of USDM and standard APIs.
Typically, there are multiple eCRF reviewers - Clinical programmers, data managers, and other functional reviewers. eCRF creation is manual with multiple rounds of review.	**WAYS OF WORKING** — Requires understanding of USDM, and awareness of system integrations to work in an improved, automated study setup. Shortened eCRF review times are possible due to automation enabled by Biomedical Concepts structured formats and data elements. The association of biomedical concepts with protocol activities and assessments in a structured manner vs. narrative text helps internally standardize study data collection by defining what data and how to capture it.

BIGGEST AREA FOR IMPACT

- Updates expected to SOPs, processes, working instructions, and templates.
- Introduces new or updated **USDM-compliant tools/systems capable of digital exchange of information** using standard APIs.

RECOMMENDED ACTION FOR IMPACT

- Deliver **change management toolkit** to support change associated with DDF. This can include technical user guides/implementation guide for USDM that can be adapted to each company's ecosystem.
- **Provide reskilling** on new processes, tools and software implemented.
- Make available **education materials and training** to help data managers understand what's new and what's changing in their role for study start-up programming.

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STUDY CONDUCT MANAGEMENT

CURRENT STATE

Study conduct management and data collection are often manual, time consuming and error prone due to greater number of manual interventions/ efforts

FUTURE STATE***

Accelerated and efficient study conduct management due to automated, digitized processes leading to fewer amendments and optimized data collection

Process involves amendment and migration management, data entry review, query management, and data review of pivotal data. Manual snapshots for data analysis deliverables.

PROCESS

Fewer amendments are expected with the availability of digitized protocol, including an opportunity for faster, more efficient automated amendments. Optimal data collection and design could reduce the data inconsistencies between eCRF versions.

Currently leverages EDC system, coding tool, external data reports.

TECHNOLOGY

Integrates EDC system with SDR** and other systems.

Data Managers, other functional data reviewers, sites, and CRAs with risk-based monitoring are involved in study conduct. Manual collaborative and data collection efforts across different groups mean more data is collected, leading to more review and greater effort prone to errors.

WAYS OF WORKING

Potentially captures greater efficiencies as automation reduces the number of tasks required to be completed.

BIGGEST AREA FOR IMPACT

- **Reduces amendments, improves data collection, provides better data quality, reduces errors and inefficiencies** in eCRF design and data capture.
- Reduces time spent on data cleaning.

RECOMMENDED ACTION FOR IMPACT

- **Provide use cases** for reduction in amendments, cost and time efficiencies in query generation, reduction in number of checks required.

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DATA STANDARDS

CURRENT STATE
Relies on a company's internal library/standards

FUTURE STATE***
Data standards shift to use of CDISC USDM

PROCESS

Adheres to internal data standards during eCRF development..

Data standards are remapped to USDM model.

TECHNOLOGY

Uses an Internal content library with eCRF standards, dictionaries and codelists.

Content library is aligned to biomedical concepts structure enabled by the USDM and standard APIs.

WAYS OF WORKING

Governance is in place for data mapping, codelists, and standard terminology based on internal company policies.

Governance is in place for data mapping, codelists, and standard terminology, including impacts from USDM updates.

BIGGEST AREA FOR IMPACT

- Builds understanding of the digitized data structured protocol and outputs, USDM** or any study repository and biomedical concepts.

RECOMMENDED ACTION FOR IMPACT

- Provide **user/implementation guides** for mapping considerations, existing models.
- Make available **education materials** to help data managers understand what's new and what's changing in their roles across process and technology for data standards management.

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“Day in the Life” with Digital Data Flow (DDF) Initiative

“I am responsible for setting up a study in an EDC system to collect, organize, manage, and validate incoming clinical data as per the protocol content, and for overseeing and coordinating the associated clinical data capture processes. The DDF initiative enables me to focus on data collection and quality strategy, higher value work that has a critical impact on data management deliverables and outcomes for a study and across the molecule program" - ***Sienna, Clinical Data Manager****

AM

8 AM

Sienna starts her day with a review of the digital protocol, with a focus on SoA and digital data fields, metadata that will be used in automation of eCRF build in EDC. **Working in a digitized, automated environment enabled by the DDF initiative could streamline data management processes, introduce cost, time and quality efficiencies freeing up time to work on high-value creation services, including innovation, data analytics and quality enhancement** ↻

Sienna asks the clinical science and safety scientist, PK and Biomarker scientists for further information on the pertinent scientific rationale of the clinical study during protocol review to identify priority areas and ensure data flow into EDC system.

At the weekly Team meeting, Sienna discusses any study build issues, data cleaning requirements, resource issues, non-eCRF requirements, team alignment on deliverable due dates, and answers any questions regarding the digital protocol.

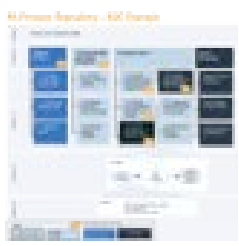
With the DDF solution components, such as the USDM, Sienna can shift focus to strategic, high value-added tasks as repetitive and tactical workflows are automated. Reduced end to end cycle time provides Sienna bandwidth to focus her work on value creation and innovative activities. ↻

Sienna shares with her data management team the digital protocol and SOA for their awareness and input regarding downstream impacts. 💻

She later discusses the digital protocol at a molecule/program level to ensure alignment across the program so that the data can be pooled across multiple studies for analysis and re-use for data insights and metrics.

A digitized protocol and USDM generate rich structured data content and metrics, providing digital insights to help Sienna and her team make better informed decisions. 💻

11 AM



Sienna attends an eCRF design review meeting to collect study team feedback and share draft annotated eCRF.

With the availability of structured data and digitized study design formats enabled by USDM required study protocol content could be available in the first round of study data collection. ↻

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↻ *Process*
💻 *System/Technology*
✪ *Ways of working*

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PM

Sienna works with the project team to discuss the critical data in the digital protocol and SOA to create a critical data review/ cleaning mitigation plan.

A digitized, automated environment could allow Sienna to spend more of her time on such value creation activities and less on manual work in setting up EDC, eCRF. ✪

Sienna completes a self-paced e-learning module on the USDM to stay on top of system upgrades and process redesign updates. ✪

2 PM

Sienna attends virtual training on the overview of the digital protocol and review process in the study builder tool. She also attends training on SOPs and process updates as a result of DDF implementation.

Training on USDM enabled process changes, system upgrades and SOPs enable Sienna to work effectively and extract maximum value. ✪

Sienna attends UAT review of the EDC build and associated edit checks as well as addressing any system integration issues between the SDR and EDC system. ↻

Sienna works with the project team to define tracking and readiness process metrics. 💻
She receives a metrics report from the clinical programmer on the most frequently collected eCRFs, data fields, dictionaries that have the highest impact on analysis outputs for her study deliverables. She also receives higher level metrics across the molecule program, metrics of data with the lowest impact for consideration in future study development. She discusses metrics with her study team and with the program lead.
The digitalization of end-to-end processes from study design to EDC generates structured data that can be leveraged to track outcomes, trends, and progress made. ↻

Sienna completes periodic pulse check surveys to provide feedback on EDC automation and impact of DDF on her role and work.

The Change Champion on Sienna’s team shares the latest updates and collects and collates the feedback. ↻

A digitized, automated environment has freed up time for Sienna.

She uses this freed-up time to review upcoming timelines for study build completion and projected study deliverables such as the first data monitoring deliverable. Sienna assesses any risks to timelines. ↻

5 PM

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↻ *Process*
💻 *System/Technology*
✪ *Ways of working*

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